MAR 1 6 2001

K004014 p1/2

510(k) SUMMARY

1. Applicant:	General Project	
2. Address:	Via della Gora 13/1 50025 Montespertoli Florence, Italy	
3. Contact Persons:	Cornelia Damsky Tel: Moreno Naldoni Tel	(203) 323-7535 ++39 0571 675076
4. Preparation Date:	December 16, 2000	
5. Device Submitted:	MD 30 COMPACT Diode Laser and accessories	
6. Proprietary Name:	MD 30 COMPACT	
7. Common Name:	Diode Laser	
8. Classifiaction Name:	Laser surgical instrument for use in General and Plastic Surgery and in Dermatology. Product Code GEX, Panel 79	
10. Predicate Device:	The MD 30 COMPACT is substantially equivalent to the followig currently marketed devices: Diomed's LaserLite Diode Surgical Laser System, Coherent Star 's Light Sheer Pulsed Diode Array Laser System and Nidek Inc.'s Epi-Star Diode Surgical Laser System	
11. Device Description:	The MD 30 COMPACT is a microprocessor controlled laser system, which uses a GaAlAs diode laser laser tube that produces a 808 nm ± 5 nm wavelength of near infrared energy. The four principal parts of the system include the laser source with power supply and thermoelectric cooler (Peltier cells), electronic control system, fiberoptic with handpiece and a control panel.	
12. Intended Use:	The MD 30 COMPACT is intended for the treatment of pigmented and vascular lesions including leg veins, spider veins and telangiectasis. The MD 30 COMPACT is also indicated for hair removal.	
13. Legally-Marketed Predicate Device:	Diomed's LaserLite Diode Surgical Laser System, Coherent Star's Light Sheer Pulsed Diode Array Laser System and Nidek Inc.'s Epi-Star Laser System	

14. Performance Data:	No performance data is required for this Class II device nor requested by the Food and Drug Administration (Office of Device Evaluation). A data base search has been performed to evaluate any adverse effects of the device that is currently marketed. No data submitted for section 807.92 6[(b)(1)(2)(3c)].

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 6 2001

General Project
c/o Ms. Cornelia Damsky
Regulatory Consultant
Cornelia Damsky, Inc.
56 Westcott Road
Stamford, Connecticut 06902

Re: K004014
Trade Name: MD 30 COMPACT Diode Laser
Regulatory Class: II
Product Code: GEX
Dated: December 22, 2000
Received: December 22, 2000

Dear Ms. Damsky:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Performer 30 HPS K004014

This product is intended to be used by surgeons for the incision, excision, and vaporization of soft tissue in the following:

- Hair removal
- Treatment of pigmented and vascular lesions including leg veins, spider veins and telangiectasis.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K004014

Prescription Use ✓
(Per 21 CFR 801.109)